

Food and Drug Administration Silver Spring, MD 20993

### TRANSMITTED BY FACSIMILE

Kavita Srivastava Executive Director, Regulatory Affairs Taro Pharmaceuticals USA, Inc. 3 Skyline Drive Hawthorne, NY 10532

**RE:** NDA # 018613

Ovide® (malathion) lotion, 0.5%

MACMIS #19661

Dear Ms. Srivastava:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a book titled, "There's a Louse in My House" (book) for OVIDE® (malathion) lotion, 0.5% (Ovide), which was disseminated by Taro Pharmaceuticals USA, Inc. (Taro) at the 2010 American Academy of Physician Assistants conference held in Atlanta, GA and submitted under cover of Form FDA-2253. The book is misleading in that it presents efficacy claims for Ovide, but fails to include any risks associated with its use. Thus, the book misbrands Ovide in violation of the Act, 21 U.S.C. 352(a) & 321(n). *Cf.* 21 CFR 202.1(e)(5).

# Background

According to the INDICATIONS AND USAGE section of the FDA-approved product labeling (PI) for Ovide:

OVIDE Lotion is indicated for patients infected with <u>Pediculus humanus capitis</u> (head lice and their ova) of the scalp hair. (emphasis in original)

The CONTRAINDICATIONS section of the PI states:

OVIDE Lotion is contraindicated for neonates and infants because their scalps are more permeable and may have increased absorption of malathion. OVIDE Lotion should also not be used on individuals known to be sensitive to malathion or any of the ingredients in the vehicle.

The WARNINGS section of the PI states (in pertinent part):

OVIDE Lotion is **flammable** (emphasis in original). The lotion and wet hair should not be exposed to open flames or electric heat sources, including hair dryers and electric curlers. Do not smoke while applying lotion or while hair is wet. Allow hair to dry naturally and to remain uncovered after application of OVIDE Lotion.

Reference ID: 2916921

OVIDE Lotion should only be used on children under the direct supervision of an adult.

If OVIDE Lotion comes into contact with the eyes, flush immediately with water. Consult a physician if eye irritation persists.

If skin irritation occurs, discontinue use of product until irritation clears. Reapply the OVIDE Lotion, and if irritation reoccurs, consult a physician.

Slight stinging sensations may occur with the use of OVIDE Lotion.

#### General:

Keep out of reach of children. Close eyes tightly during product application. If accidentally placed in the eye, flush immediately with water. Use only on scalp hair.

### Information to Patients:

In case of accidental ingestion of OVIDE Lotion by mouth, seek medical attention immediately.

If you are pregnant or nursing, you should contact your physician before using OVIDE Lotion.

Apply OVIDE Lotion on the scalp hair in an amount just sufficient to thoroughly wet hair and scalp. Pay particular attention to the back of the head and neck when applying OVIDE Lotion. Anyone applying OVIDE Lotion should wash hands immediately after the application process is complete.

Allow hair to dry naturally and to remain uncovered. Shampoo hair after 8 to 12 hours, again paying attention to the back of the head and neck while shampooing.

Rinse hair and use a fine-toothed (nit) comb to remove dead lice and eggs.

If lice are still present after 7-9 days, repeat with a second application of OVIDE Lotion.

Further treatment is generally not necessary. Other family members should be evaluated by a physician to determine if infested, and if so, receive treatment.

### The ADVERSE REACTIONS section of the PI states:

Malathion has been shown to be irritating to the skin and scalp. Accidental contact with the eyes can result in mild conjunctivitis.

It is not known if OVIDE Lotion has the potential to cause contact allergic sensitization.

#### **Omission of Risk Information**

Promotional materials are misleading if they fail to reveal facts that are material in light of representations made or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. 21 U.S.C. 321(n).

In this case, the front cover of the book displays the title, "There's a Louse in My House" and a cartoon of a young girl observing a large insect shadow, as well as the drug name, "Ovide," with its established name malathion, dosage form and strength, in conjunction with the tagline "Prescribe with Confidence." (emphasis in original). The title page likewise includes the book title, drug name, dosage form, strength and tagline, as well as a cartoon of a young girl examining lice through a magnifying glass. The theme of the ensuing story is a young girl infected with head lice and the interventions that her mother takes to remove the lice on her head and on other objects such as the bed, bed sheets, and toys. The totality of this presentation makes the representation that Ovide is indicated and prescribed for the treatment of head lice. However, the book entirely omits all risk information associated with the drug product. By omitting the most serious and frequently occurring risks associated with the drug, the book misleadingly suggests that Ovide is safer than has been demonstrated.

## **Conclusion and Requested Action**

For the reasons discussed above, the book misbrands Ovide in violation of the Act, 21 U.S.C. 352(a) & 321(n). *Cf.* 21 CFR 202.1(e)(5).

DDMAC requests that Taro immediately cease the dissemination of violative promotional materials for Ovide such as those described above. Please submit a written response to this letter on or before March 25, 2011, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Ovide that contain violations such as those described above, and explaining your plan for discontinuing use of such violative materials. Please direct your response to me at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, 5901-B Ammendale Road, Beltsville, MD 20705-1266, facsimile at 301-847-8444. In all future correspondence regarding this matter, please refer to MACMIS # 19661 in addition to the NDA number. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for Ovide comply with each applicable requirement of the Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Sheetal Patel, PharmD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

Reference ID: 2916921

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/s/	
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